UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,965	02/11/2002	Jean-Luc Balligand	DCLERC-2 P1	2383

23599 7590 07/02/2004

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER	
NGUYEN, QUANG	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 07/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/068,965	BALLIGAND ET AL.	
	Examiner	Art Unit	
	Quang Nguyen, Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *38-78* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants' amendment filed on 10/2/03 has been entered.

A new set of claims 37-78 are pending in the present application. In the amendment filed on 4/8/04, Applicants elected with traverse the invention of Group XII, drawn to an antagonist of caveolin-1 as a compound for use as a medicament for the modulation of angiogenesis in response to the Restriction Requirement mailed on 8/12/03. As an antigonist of caveolin-1 is defined in the present application as any molecule that can antagonize the function of caveolin-1 per se or acts as a competitive inhibitor by inhibiting the binding of binding partners, including a scavenging molecule or a molecule able to trap caveolin-1 (see specification page 11, lines 3-11).

Upon reconsideration and in light of a new set of claims being submitted, new pending claims 37-78 are subjected to the following restriction.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group Restriction

I. Claims 38-42, 47, 72, 74-77, drawn to a pharmaceutical composition for modulating angiogenesis comprising a therapeutically effective amount of a recombinant caveolin-1, a nucleic acid encoding the partial or total amino acid sequence of caveolin-1 or an agonist of caveolin-1, a method of modulating angiogenesis comprising overexpressing or improving the activity of caveolin-1 and a method for the treatment of an angiogenesis

related disease using the same, classified in class 514, subclasses 2, 44; for example.

II. Claims 42-52, 67-71, 73-78, drawn to a pharmaceutical composition for modulating angiogenesis comprising a therapeutically effective amount of an angiogenesis modulating compound, wherein said angiogenesis modulating compound is an antisense nucleic acid which hybridizes with a sequence coding the partial or total amino acid sequence of caveolin-1, an antagonist of calveolin-1 or a competitive inhibitor of caveolin-1 or a scavenging or trapping molecule, a kit comprising the same, a method of modulating angiogenesis comprising trapping endogenous caveolin-1 by a trapping compound, a method of modulating angiogenesis comprising reducing abundance and/or activity of caveolin-1, and a method for the treatment of an angiogenesis related disease using the same, classified in class 514, subclasses 2, 44, for example.

III. Claims 54-58, 66, 72, 74-77, drawn to a pharmaceutical composition for modulating angiogenesis comprising a therapeutically effective amount of a recombinant hsp90 or a nucleic acid encoding the partial or total amino acid sequence of hsp90 or an analogue thereof, or an agonist of hsp90, a medicament comprising hsp 90, a kit comprising the same, a method of modulating angiogenesis comprising overexpressing or improving the activity of hsp90 and a method for the treatment of an angiogenesis

related disease using the same, classified in class 514, subclasses 2, 44, for example.

IV. Claims 58-63, 73-77, drawn to a pharmaceutical composition for modulating angiogenesis comprising a therapeutically effective amount of an angiogenesis modulating compound, wherein said angiogenesis modulating compound is an antisense nucleic acid which hybridizes with a sequence coding the partial or total amino acid sequence of hsp90, an antagonist of hsp90 or a competitive inhibitor of hsp90, a kit comprising the same, a method of modulating angiogenesis comprsing reducing abundance and/or activity of hsp90, and a method for the treatment of an angiogenesis related disease using the same, classified in class 514, subclass 44, for example.

V. Claim 64, drawn to a composition comprising a statin and hsp90 or a pharmacologically acceptable derivative thereof, classified in class 514, subclass 2, for example.

VI. Claim 65, drawn to a composition comprising a growth factor and hsp90 or a pharmacologically acceptable derivative thereof, classified in class 514, subclass 2, for example.

The inventions are distinct, each from the other because of the following reasons:

The pharmaceutical compositions of Groups I-VI are distinct in chemical components that have different properties one from the others. For example, the pharmaceutical composition of Group I includes a recombinant caveolin-1, a nucleic

acid encoding the partial or total amino acid sequence of caveolin-1 or an agonist of caveolin-1 which have different properties from the pharmaceutical composition of Group II which comprises an antisense nucleic acid which hybridizes with a sequence coding the partial or total amino acid sequence of caveolin-1, an antagonist of calveolin-1 or a competitive inhibitor of caveolin-1 or a scavenging or trapping molecule of caveolin-1. Agonists and antagonists of caveolin-1 are distinct chemically and structurally from agonists and antagonists of hsp90 present in the pharmaceutical compositions of Groups III and IV, respectively. None of the pharmaceutical compositions of Groups I-IV requires specifically statin and hsp90 as components for the composition of Group V or a growth factor and hsp90 as components for the composition of Group VI. Furthermore, neither the composition of Group V or VI is required for any of the methods of Groups I-IV.

The methods of Groups I-IV are distinct one from the others because they have different starting materials (see the reasons already set forth in the preceding paragraph) and different desired end-results (overexpressing and improving the activity of caveolin of Group I vs reducing the abundance and/or activity of caveolin-1 of Group II vs overexpressing and improving the activity of hsp90 of Group III vs reducing the abundance and/or activity of hsp90 of Group IV), and therefore they require different technical considerations for achieving the desired results.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and separate search requirements (e.g., different classification as well as

different literature searches), it would be unduly burdensome for the examiner to search and/or consider the patentability of all the inventions in a single application. Therefore, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).

Species Restriction

A. Should Applicants elect the invention of Group I, this application contains claims directed to patentably distinct species of **an agonist of caveolin-1** (e.g., a recombinant caveolin-1, a nucleic acid encoding the partial or total amino acid sequence of caveolin-1, and other agonist molecules).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species that does not read on another narrower species in the claims for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 38, 42, 47, 72, 74-77 are generic.

B. Should Applicants elect the invention of Group II, this application contains claims directed to patentably distinct species of **an antagonist of caveolin-1** (e.g., SEQ ID NO: 2, SEQ ID NO:3, SEQ ID NO:5, SEQ ID NO:4, one of SEQ ID NOs: 6-86).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species that does not read on another narrower species (for example one of the aforementioned SEQ ID NOs) in the claims for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 42, 43, 47-52, 67-71, 73-77 are generic.

C. Should Applicants elect the invention of Group III, this application contains claims directed to patentably distinct species of **an agonist of hsp 90** (a recombinant hsp 90 or a nucleic acid encoding the partial or total amino acid sequence of hsp 90, for example).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species that does not read on another narrower species in the claims for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 54, 56, 58, 72, 74-77 are generic.

D. Should Applicants elect the invention of Group IV, claims 58-59, 62-63, 73-77 are generic to a plurality of disclosed patentably distinct species of **antagonist of hsp90** including an antisense nucleic acid which hybridizes with a sequence coding the partial or total amino acid sequence of hsp90, various competitive inhibitors or antagonists of hsp90 disclosed in the specification.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species that does not read on another narrower species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims

readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, David Guzo, Ph.D., may be reached at (571) 272-0767, or SPE, Irem Yucel, Ph.D., at (571) 272-0781.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1636; Central Fax No. (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now

contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Quang Nguyen, Ph.D.

REMY YUCEL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600